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John P. White
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30 Rockefeller Plaza
New York, NY 10112

Re: Patent Term Extension
Application for
U.S. Patent No. 4,529,593

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,529,593 issued July 16, 1985, which claims the human drug product Ganite, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 915 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 6, 1991. Under 35 USC § 156 (c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (1,345) + 669 \\ &= 1,342 \text{ days}\end{aligned}$$

Since the regulatory review period began November 10, 1973, before the patent issue date, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. The period of time from the start of the regulatory review period on November 10, 1973, up to the issuance of the patent on July 16, 1985, is 4,265 days. This period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $5,610 - 4,265 = 1,345$ days. No determination of a lack of due diligence was made.

The 14 year exception of 35 USC § 156 (c) (3) operates to limit the term of extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (January 17, 1991) when added to the period of extension calculated above (1,342 days) cannot exceed fourteen years. The period of extension is thus limited to January 16, 2005, by operation of 35 USC § 156 (c) (3). Since the patent term of seventeen years (35 USC § 154) would expire on July 16, 2002, the period of extension is the number of days to extend the term of the patent from this time to January 16, 2005, or 915 days.

The limitations of 35 USC § 156 (g) (6) do not operate to further reduce the period of extension determined above.

U.S. Patent No. 4,529,593

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136 (a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,529,593 a certificate of extension, under seal, for a period of 915 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,529,593
Granted:	July 16, 1985
Applicant:	Warrell, Jr. et al
Owner of Record:	Sloan-Kettering Institute for Cancer Research
Title:	USE OF GALLIUM SALTS TO TREAT DISORDERS OF CALCIUM HOMEOSTASIS
Classification:	514/411
Product Trade Name:	Ganite
Term Extended:	915 days

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Programs Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Ganite
FDA Docket No.: 91E - 0124